DIPHENHYDRAMINE HCL - diphenhydramine hcl capsule Bryant Ranch Prepack

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient(in each capsule)

Diphenhydramine HCL 50 mg

Purpose

Antihistamine

Uses:

- Temporarily relieves these symptoms associated with the common cold, hay fever, or other respiratory allergies.
- Sneezing.
- Nasal congestion.
- Runny nose.
- Itchy, watery eyes.

Warnings:

Do not use

• With any other product containing Diphenhydramine HCL, including one applied topically.

Ask a doctor or pharmacist before use

If you have Trouble urinating due to enlarged prostate gland A breathing problem such as emphysema or chronic bronchitis Glaucoma If you are taking sedatives or tranquilizers

When using this product

- Avoid alcoholic drinks.
- Marked drowsiness may occur.
- Excitability may occur, especially in children.
- Alcohol, sedatives and tranquilizers may increase drowsiness.
- Be careful when driving a motor vehicle or operating machinery.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions:

Take every 4-6 hoursDo not take more than 6 doses in 24 hours. Adults and children 12 years or over1 capsule Children under 12 years ask a doctor**25 mg strength is not available in this package. Do not attempt to break capsules.

Other information:

- Store at room temperature 15-30 degrees C (59-86 degrees F)
- Protect from excessive moisture

Inactive ingredients: Black Iron Oxide, D & C Red #28, FD & C Blue #1, FD & C Red #40, Gelatin, Lactose Monohydrate, Magnesium Stearate, Silicon Dioxide, Sodium Lauryl Sulfate

Questions? Adverse drug event call:

1-800-687-0176

HOW SUPPLIED

Product: 71335-0526

NDC: 71335-0526-1 15 CAPSULE in a BOTTLE

NDC: 71335-0526-2 20 CAPSULE in a BOTTLE

NDC: 71335-0526-3 30 CAPSULE in a BOTTLE

NDC: 71335-0526-4 10 CAPSULE in a BOTTLE

NDC: 71335-0526-5 6 CAPSULE in a BOTTLE

NDC: 71335-0526-6 100 CAPSULE in a BOTTLE

NDC: 71335-0526-7 90 CAPSULE in a BOTTLE

NDC: 71335-0526-8 60 CAPSULE in a BOTTLE

NDC: 71335-0526-9 2 CAPSULE in a BOTTLE

NDC: 71335-0526-0 12 CAPSULE in a BOTTLE

Diphenhydramine 50mg Capsule



DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71335-0526(NDC:66424-021)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6 JAD40) (DIPHENHYDRAMINE UNII:8GTS82S83M)
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Inactive Ingredients					
Ingredient Name	Strength				
FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357)					
D&C RED NO. 28 (UNII: 767IP0 Y5NH)					
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)					
FD&C RED NO. 40 (UNII: WZB9127XOA)					
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)					
LACTO SE MO NO HYDRATE (UNII: EWQ57Q8 I5X)					
MAGNESIUM STEARATE (UNII: 70097M6I30)					
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)					
SODIUM LAURYL SULFATE (UNII: 368GB5141J)					

Product Characteristics					
Color	pink	Score	no score		
Shape	CAPSULE	Size	14mm		
Flavor		Imprint Code	PH0 13		
Contains					

Packaging							
#	Item Code	Package Description Marketing St		rt Date Marketing End Date			
1	NDC:71335-0526-1	15 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/27/20 10				
2	NDC:71335-0526-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/27/20 10				
3	NDC:71335-0526-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/27/20 10				
4	NDC:71335-0526-4	10 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/27/20 10				
5	NDC:71335-0526-5	6 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/27/20 10				
6	NDC:71335-0526-6	OC:71335-0526-6 100 in 1 BOTTLE; Type 0: Not a Combination Product					
7	NDC:71335-0526-7	90 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/27/20 10				
8	NDC:71335-0526-8	C:71335-0526-8 60 in 1 BOTTLE; Type 0: Not a Combination Product					
9	NDC:71335-0526-9	2 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/27/20 10				
10	NDC:71335-0526-0	12 in 1 BOTTLE; Type 0: Not a Combination Product	0 1/27/20 10				
Marketing Information							
Marketing Category Application Number or Monograph Citation		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
ОТ	OTC monograph final part341		0 1/27/20 10				

Labeler - Bryant Ranch Prepack (171714327)

Establishment						
Name	Address	ID/FEI	Business Operations			
Bryant Ranch Prepack		171714327	REPACK(71335-0526), RELABEL(71335-0526)			

Revised: 1/2020 Bryant Ranch Prepack